



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/563,828

05/08/2006

Per Wollmer

613-101

1945

23117 7590 01/15/2010
NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

01/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,828	Applicant(s) WOLLMER ET AL.	
	Examiner JAGADISHWAR R. SAMALA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of Applicant's Arguments and Remarks filed on 10/27/2009.

- Claims 19-27 are pending in the instant application.

Response to Declaration under CFR § 1.132

Applicant's Declaration of Tomas Landh submitted under 37 CFR § 1.132 filed on 10/27/2009 has been acknowledged and entered into the application.

Applicant's Declaration has been fully considered, but is not persuasive. The declaration states the traditional emulsions are the opaque dispersion of one phase in another which is familiar to most scientists. These are cloudy since they contain stabilized droplets of one phase suspended within another and also states that microemulsions are based on mixtures of polar and non-polar lipids which typically form transparent, thermodynamically stable. The declaration states that it is necessary to have at least around 20% glycerol monooleate to form reversed phase microemulsion, but does not mention that instant invention is a reversed phase microemulsion. The prior art also teaches emulsion having a polar phase mixed with a non-polar lipids with minimum amounts of surfactants which would lead to a reversed phase emulsion. Since the declaration does not enumerate the components, amounts, or conditions used, it is not clear if the composition obtained by Applicants in the declaration is same as the reversed phase microemulsion would generally have water-in-oil phase.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claims 19 and 20 to recite "reversed phase" microemulsion. This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The specification discloses a composition comprising glycerol monooleate 34%, propylene glycol 23%, PEG 18%, sesame oil 11%, and saline solution 10% as a microemulsion suitable for entrapping airborne particles. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. §112.

Art Unit: 1618

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to identify sufficient written support in the original specification for the "limitations" indicated above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al (US 6,506,803) in view of Wright (US 6,618,840) are withdrawn in view of Applicant's arguments filed on 10/27/2009.

However, upon further consideration a new ground(s) of rejection is prepared as follows.

Art Unit: 1618

Claims 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Linn et al (4,797,273) in view Rudnic et al (US 5,897,876).

Applicant claims are drawn to a reversed phase microemulsion comprising 5 to 35 wt% of a non-polar animal or vegetable oil; 10 to 55 wt% of at least one polar solvent; at least one surfactant; and 20 to 50 wt% of a monoacyl glycerol wherein vegetable oil is sesame oil, polar solvent is propylene glycol and surfactant has a hydrophilic-hydrophobic balance exceeding 7.

Linn teaches water-in-oil microemulsion composition comprising from about 3.0% to about 35% weight of vegetable oil, from about 20.0% to about 80.0% of microemulsion forming surfactant reads on alcohol and from about 5.0% to about 50.0% of skin humectants (abstract and col. 4 lines 35-40). The water-in-oil microemulsion reads on reversed phase microemulsion. The vegetable oil includes sesame oil (col. 5 line 50). The microemulsion forming surfactant includes sorbitans, poloxamers (col. 6 lines 18-20). The humectants include polyhydric alcohols such as propylene glycol, glycerol (col. 6 lines 46-47). Additional disclosure includes that the compositions are useful for a variety of purposes, especially for protecting the skin's surface when applied to skin since they leave little residue on the surface of the skin following their application and further are generally not irritating to the skin when formulated with the proper balance of non-ionic surfactants.

Linn fails to teach microemulsions further comprising a monoacyl glycerol in the composition/

Art Unit: 1618

Rudnic teaches a water-in-oil microemulsion an oily phase, composed of long chain fatty acids or esters or alcohols, an aqueous phase composed of water, and a surface active agent, primarily of the non-ionic block copolymer type, that are mixed together to form a water-in-oil microemulsion (col. 3 lines 47-54). The long chain carboxylic acid esters include glyceryl monooleate, glyceryl monolinoleate (col. 4 lines 19-20), poloxamers in amounts of about 0.05% to about 50.0% (col. 5 lines 29-30). The aqueous phase further comprises Hank's buffer to maintain the pH of the composition 5.0 and 7.0 (col. 15 table 13-16). Additional disclosure includes that the advantage of water-in-oil microemulsion has the ability to dissolve relatively large amounts of polar solutes in an overall oily environment, creating an oral delivery system for peptide and protein drug molecules (col. 2 lines 31-35).

Cho teaches a water-in-oil microemulsion formulation comprising phospholipoprotein or other complex, surfactant such as glyceryl monooleate, polysorbate 80 (col. 9 lines 25-28), vegetable oil such as sesame oil (col. 9 lines 63+). The formulation contains hydrophilic-hydrophobic balance greater than 10 (col. 6 lines 43-45). The pH of water-phase solution is adjusted to 7.2 with 0.1M NaCl/10mM sodium phosphate buffer (col. 15 lines 45-56). Additional disclosure includes that the added sesame oil to the microemulsion has anti-oxidant activity and further advantage that it improves the flavor of the formulation, thereby improving patient compliance (col. 9 lines 63+).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate monoacyl glycerol such as glyceryl monooleate into Linn's composition. The person of ordinary skill in the art would have been motivated to make

Art Unit: 1618

those modifications because microemulsions containing an oil phase such as long chain carboxylic acid or ester or alcohols, has the ability to dissolve relatively large amount of polar solutes in an overall oily environment. Further Rudnic teaches that certain hydrophobic materials such as glyceryl monooleate, glyceryl monolinoleate, when emulsified in a continuous phase of a hydrophilic material (water-in-oil microemulsion) provides enhanced absorption capabilities for oral delivery of peptide drugs and drugs that are poorly soluble in aqueous media (col. 3 lines 38-43). Therefore, one of ordinary skill in the art would have had a reasonable expected success because it was well known in the art that monoacyl glycerol (such as glyceryl monooleate or glyceryl monolinoleate) are highly compatible for oral delivery system and support for the dispersing and co-emulsifying action in microemulsion compositions.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr